UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,665	08/13/2001	Neil H. Bander	266/187	9976

26161 7590 06/24/2005

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/929,665
Filing Date: July 20, 1999
Appellant(s): BANDER, NEIL H.

Laurie Butler Lawrence
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 2, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection/Arguments

Written Description/New Matter. This rejection is maintained for the reasons of record and for the reasons set forth below:

Appellants argue that the instant application provides explicit and/or implicit written description support for the disputed claim terminology of "competes for binding to prostate membrane antigen with a monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and J591 monoclonal antibody" (i.e. Claim 144).

Appellants argue that the written description requirement is met if the specification shows that an Appellant was in possession of the claimed invention at the time of filing. Appellants further refer to several court decisions: ***in Re Smith, Purdue Pharma v. Faulding, Inc.***, *and* ***In re Wright*** to conclude that that the original disclosure need not provide literal support or exact wording for claimed subject matter (Brief, page 6).

Appellants note that the claimed invention involves a method that uses an antibody having a specific feature: it competes for binding to PSMA (prostate specific membrane antigen) with a specific, disclosed antibody, namely E99, J591, J415, or J533. Appellants further provided a Declaration by Abbie Celniker under 37 CFR 1.132 which proposes that the specification, on page 27, lines 26-35, indicates that Appellant was in *possession* of antibodies that compete for binding with J415, J591, J533 or E99.

Appellant's arguments and the Declaration have been carefully considered, but are not found persuasive. As set forth previously, the specification only provides a written description and indicates possession of a genus of antibodies that bind to the extracellular domain of PSMA

and four species of such monoclonal antibodies, or *species* of the genus, e.g. E99, J591, J415, or J533.

The rejected claims, (i.e. those covering a subgenus of antibodies that "compete for binding" to E99, J591, J415, or J533) are not representative of the above genus or species because they constitute a separate subgenus of monoclonal antibodies. The specification fails to recite or reasonably contemplate or indicate possession of said subgenus. As set forth previously, it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Appellants have continued to argue that the disclosure (page 27, lines 26-35) indicates that they are in possession of all such competing antibodies. This argument has been considered previously but is not found persuasive. Appellants have further reprinted the Examiner's analysis (Brief, pages 7, and 10) and argue that the disputed passage was misinterpreted because it does not rule out the use of competing antibodies. Appellants argue (Brief, top of page 11) that the inventor "could have used" more restrictive language such as "competing antibodies are not suitable for use in prodrug/activator systems". This argument has been considered but is not found persuasive. Although this particular passage may not necessarily exclude the use of competing antibodies, the issue is whether or not Appellants have fully described the scope of the claims; a subgenus of antibodies that compete for binding to PSMA with the species of monoclonal antibodies--- E99, J415, J533, and J591. In this particular case, the written description requirement for the claimed genus of antibodies that bind to the extracellular domain of PSMA are satisfied through sufficient description of a representative number of the latter

species of monoclonal antibodies. However, the same cannot be said for the claimed "subgenus" of antibodies because Appellants have not identified a representative number of species that adequately describe the entire subgenus. Further, antibodies that encompass the subgenus of "competing" antibodies would include substantial variation because the disclosed species of antibodies (i.e. E99, J415, J533, and J591) include those that bind to different epitopes on the PSMA molecule. Furthermore, competing antibodies could include any antibodies that hinder binding such as those that differ in size. Thus, it cannot be said that one of ordinary skill in the art would recognize (either implicitly or explicitly) that Appellants were in possession of the claimed subgenus because the disclosure fails to describe a sufficient variety of species to reflect the variation within the subgenus.

Appellants further argue (Brief, page 12) that the Examiner's analysis was based on "unfounded assumptions or factual error" about the prodrug/activator system. Appellants further argue that no reasonable basis was presented that supports the Examiner's view that a competing antibody would be inappropriate for the prodrug system. This argument has been considered and is not found persuasive. On the contrary, the examiner raised reasonable scientific concerns (Advisory Action, 04-20-2004, page 4) regarding competing antibodies and why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the claimed subgenus. Appellants only appear to argue the opposite; that competing antibodies that bind to overlapping epitopes might just as well create the needed close proximity between the prodrug and the activator.

Appellants further argue (Brief, page 12) that the rejection is based on a misapplication of the law because it relies heavily on the argument that prodrug/activator systems made with

competing antibodies will not work. Appellants argue that this analysis confuses the "utility or enablement of a prodrug/activator system (which is not the subject of the claims) "with written description of the antibody components used to make the prodrug/activator system. This argument has been considered but is not found persuasive because Appellant's alleged support of the subgenus invited the uncertainty. Further, it is not understood how the Examiner's response was misapplied because the statute underlying the first paragraph of 35 USC 112 includes issues regarding enablement and written description. Moreover, the courts appear to have indicated that operability is related to complete disclosure. See MPEP 2163.05: A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir.2004) (Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing Appellant conveyed that any other coating was suitable for a PTFE dental floss.). Appellants are also reminded of the prosecution history:

(1) Appellants presented amended claims which recited "an antibody or antigen binding portion thereof **which competes for binding to prostate specific membrane antigen with a monoclonal antibody selected from the group consisting of E99, J591, J415, or J533**"

(2) Based on the disclosures, the examiner could not find written support for the subgenus category of such antibodies and submitted a written description/new matter rejection.

(3) In their Remarks (Remarks, 03-18-2005, page 14-15) Appellants argued that the passage on page 27 lines 26-35 and page 28, lines 6-10 provided support for the new claim terminology.

In reviewing the phraseology, it was noted that the specification on page 27 disclosed "preferably one":

"The prodrug activator is conjugated with a second biological agent according to the present invention, preferably one which binds to a non-competing site on the prostate specific membrane antigen molecule.

Thus, in reviewing this phrase, the Examiner took the position that "what is preferable" is that which one of ordinary skill in the art would commonly use or recognize in a prodrug/activator scenario, i.e. non-competing ligands, probes, or antibodies or fragments thereof. To suggest that the phrase also included "competing antibodies", from a scientific standpoint, seemed illogical and the Examiner provided reasoning as to why there did not appear to be support in this particular scenario (See Advisory Action, mailed 04-20-2005)

The Declaration also suggests that preferred or not, it was clear from the disclosure that the inventors were in possession of the *idea* of an antibody which competes for binding with an antibody according to the invention. The Declaration (page 3) refers to the last sentence of the disputed passage (page 27, last sentence) which reads: "Whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding assays." However, this passage does not particularly point out nor reasonably convey whether or not Appellants were clearly in possession of a subgenus of antibodies that compete for binding to a monoclonal antibody selected from the group consisting of E99, J591, J415, or J533. In fact, the following page of the disclosure (see below and page 28, 1st paragraph) only appears to

reinforce the idea that "non-competing" antibodies are the preferred embodiment for prodrug/activator conjugates.

> For example, monoclonal antibodies J591, J533, and E99 bind to competing binding sites on the prostate specific membrane antigen molecule. Monoclonal antibody J415, on the other hand, binds to a binding site which is non-competing with the site to which J591, J533, and E99 bind. Thus, for example, the first biological agent can be one of J591, J533, and E99, and the second biological agent can be J415. Alternatively, the first biological agent can be J415, and the second biological agent can be one of J591, J533, and E99.

Clearly, the specification is reinforcing an established scientific principle; that in the context of the prodrug/activator conjugates, non-competing antibodies would be used. Thus, it is not clear why this passage would reasonably convey possession of a subgenus of "competing" antibodies when it's clearly designed to convey the use of non-competing antibodies in drug conjugate scenarios.

Appellants further refer to the decisions of *In re Lukach* and *Ex parte Sorenson* (Brief, page 15), two seemingly opposing decisions with regards to a written description of a subgenus. Appellants argue (Brief, page 17) that the present dispute is similar to the decision in *Ex parte Sorenson*, more so than *In re Lukach*. Appellants argue that when viewed from the prospective of implicit support, there is sufficient written description for the *subgenus* of antibodies that compete for binding with one of J591, E99, J415, and J533. In particular Appellants argue (Brief, page 15) that in *Ex parte Sorenson* the original application disclosed a broad genus of "copper complexes of carboxylic acids" as well as a number of species. Appellants further note that five working examples were from the originally unclaimed "sub-genus" of binuclear copper complexes of carboxylic acids. Four of these working examples were from the "sub-sub-genus"

of binuclear copper complexes of aryl carboxylic acids' and one was from the "sub-sub-genus" of binuclear copper complexes of alkyl carboxylic acids. In summarizing the case, Appellants reiterate that the Appellant (i.e., Sorenson) sought to add a claim to the sub-genus, as well as to the two sub-subgenera. Subsequently, the examiner rejected the added sub-generic and sub-sub-generic claims for lack of implicit written description and the Board reversed relying in part on *In re Kalsow.*

Appellant's analysis and comparison of this case has been considered but is not found persuasive. On the one hand, Appellants inserted the terms "sub-genus", "sub-sub-genus", "sub-generic" and "sub-sub-generic" in describing the Board's opinion. However, none of these terms appear to have antecedent basis in the actual written opinion established by the Board (see attached Board decision). The Board appears to have based their decision on the presence of working examples. For example, with regards to binuclear copper complexes of "aryl" and or "aliphatic" carboxylic acids, the Board noted five working examples of binuclear copper complexes of carboxylic acids- four were "aryl" and one was "aliphatic". There is no recitation that these examples were member of a sub-sub-genus.

Appellants provide a review of the terminology (Brief, page 16) for genus, subgenus, and species and further argue that the species of monoclonal antibodies (J591, E99, J415, and J533) fall within the broad genus of all antibodies that bind to the extracellular domain of PSMA and the relatively broad subgenus of competing antibodies. This is not found persuasive. While the four monoclonal antibodies represent species of the genus, they are not examples of species within the subgenus of "antibodies that compete for binding with one of J591, E99, J415, and J533" because members of the subgenus have yet to be discovered or produced. Thus, they

cannot include the *known* species of antibodies that bind to the extracellular domain of PSMA. Thus, there is neither implict nor explicit support for the subgenus of antibodies that compete for binding to J591, E99, J415, and J533.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05. Thus, Appellant's arguments have not been found persuasive and the rejection is maintained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER

Gary B. Nickol
June 21, 2005

Conferees:
Jeffrey Siew
Christina Chan

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
6/21/05

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600